

**510(k) SUMMARY: CALIBER® Spacers****JAN 18 2013**

**Company:** Globus Medical Inc.  
2560 General Armistead Ave.  
Audubon, PA 19403  
(610) 930-1800

**Contact:** Meriam Youssef  
Project Manager, Regulatory Affairs

**Date Prepared:** October 15, 2012

**Device Name:** CALIBER® Spacers

**Classification:** Per 21 CFR as follows:  
§888.3080 Intervertebral Body Fusion Devices.  
Product Code: MAX.  
Regulatory Class II, Panel Code: 87.

**Predicate(s):** CALIBER® Spacers (K102293)  
RISE™ Spacers (K113447)  
Kiscomedica L-Varlock™ Lumbar Cages (K080537)

**Purpose:**

The purpose of this submission is to request clearance for additional spacers with lordotic expansion, additional sizes, and sterile implants.

**Device Description:**

CALIBER® Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. CALIBER® Spacers are provided in different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral) and can expand to the desired height or the desired lordosis. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

CALIBER® Spacers are manufactured from radiolucent PEEK polymer and titanium alloy per ASTM F2026, F136 and F1295; non-expanding CALIBER® Spacers are manufactured from PEEK only. CALIBER® Spacers contain radiopaque titanium alloy or tantalum markers as specified in ASTM F136, F1295 and F560.

**Indications for Use:**

CALIBER® Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

CALIBER® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE® or REVOLVE® Stabilization Systems.

**Technological Characteristics:**

The technological characteristics of the additional CALIBER® Spacers are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics.

**Performance Data:**

Mechanical testing consisting of static and dynamic compression, static and dynamic compression-shear, and subsidence was conducted in accordance with "Class II Special Controls Guidance Document: Intervertebral Fusion Device," June 12, 2007, ASTM F2077, and ASTM F2267 to demonstrate substantial equivalence to the predicate systems.

**Basis for Substantial Equivalence:**

The additional CALIBER® Spacers are similar to the predicate systems with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject spacers to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Globus Medical Incorporated  
% Ms. Meriam Youssef  
Project Manager, Regulatory Affairs  
2560 General Armistead Avenue  
Audubon, Pennsylvania 19403

Letter dated: January 18, 2013

Re: K123231  
Trade/Device Name: CALIBER® Spacers  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: December 5, 2012  
Received: December 6, 2012

Dear Ms. Youssef:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statements

510(k) Number: K123231

Device Name: CALIBER® Spacers

### Indications:

CALIBER® Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

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Prescription Use  X  OR Over-The-Counter Use    
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S

(Division Sign-Off)

Division of Orthopedic Devices

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